

PCT/GB 2003 / U U 3 / 8 8



INVESTOR IN PEOPLE

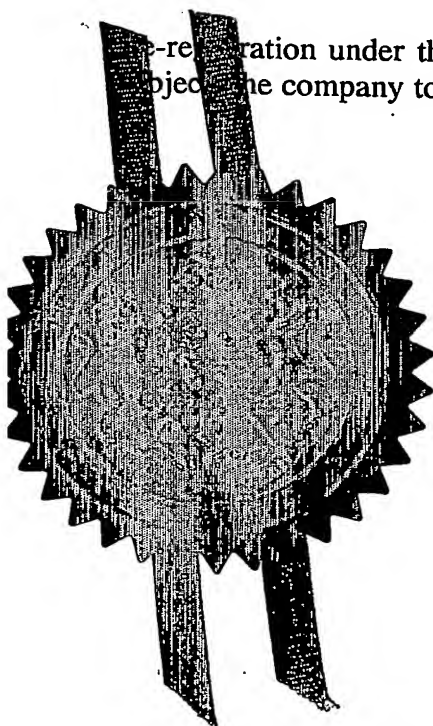
The Patent Office  
Concept House  
Cardiff Road  
Newport  
South Wales  
NP10 8QQ

I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

In accordance with the rules, the words "public limited company" may be replaced by p.l.c., plc, P.L.C. or PLC.

Re-registration under the Companies Act does not constitute a new legal entity but merely subjects the company to certain additional company law rules.



Signed *AmBrewster*

Dated 19 September 2003

**PRIORITY  
DOCUMENT**  
SUBMITTED OR TRANSMITTED IN  
COMPLIANCE WITH RULE 17.1(a) OR (b)

The  
Patent  
Office

THE PATENT OFFICE  
E

11 APR 2003

14APR03 EP0007651 D01559  
P01/7700 0.00-0308552.9

# Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

The Patent Office

Cardiff Road

Newport

Gwent NP9 1RH

1. Your reference

RH/KH/OGM3

2. Patent application number

(The Patent Office will fill in this part)

11 APR 2003

0308552.9

3. Full name, address and postcode of the or of each applicant (underline all surnames)

08295834001

Patents ADP number (if you know it)

Owen Greenings & Mumford Limited  
Stanton Harcourt Road  
Eynsham  
OXFORD  
OX29 4JB

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention

Improvements in and relating to Urine Collection  
Devices and Urine Collection Systems

5. Name of your agent (if you have one)

"Address for service" in the United Kingdom  
to which all correspondence should be sent  
(including the postcode)

Wynne-Jones, Lainé & James,

22 Rodney Road,  
CHELTENHAM,  
GL50 1JJ

Patents ADP number (if you know it)

1792001

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and (if you know it) the or each application number

Country

Priority application number  
(if you know it)

Date of filing  
(day / month / year)

GB

0219944.6

28.08.02

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application

Date of filing  
(day / month / year).

---

---

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer 'Yes' if:

Yes

- a) any applicant named in part 3 is not an inventor, or
  - b) there is an inventor who is not named as an applicant, or
  - c) any named applicant is a corporate body.
- See note (d))

# Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	0
Description	24
Claim(s)	0
Abstract	0
Drawing(s)	9

*8*

10. If you are also filing any of the following, state how many against each item.

Priority documents	---
Translations of priority documents	---
Statement of inventorship and right to grant of a patent (Patents Form 7/77)	---
Request for preliminary examination and search (Patents Form 9/77)	---
Request for substantive examination (Patents Form 10/77)	---
Any other documents (please specify)	---

11. I/We request the grant of a patent on the basis of this application.  
*Wynne-Jones, Lainé & James*  
 Signature Date  
 (Wynne-Jones, Lainé & James) 11 April 2003

12. Name and daytime telephone number of person to contact in the United Kingdom  
 R Halstead  
 (029) 2022 9526

## Warning

After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

## Notes

- If you need help to fill in this form or you have any questions, please contact the Patent Office on 0645 500505.
- Write your answers in capital letters using black ink or you may type them.
- If there is not enough space for all the relevant details on any part of this form, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s). Any continuation sheet should be attached to this form.
- If you have answered 'Yes' Patents Form 7/77 will need to be filed.
- Once you have filled in the form you must remember to sign and date it.
- For details of the fee and ways to pay please contact the Patent Office.

Improvements in and relating to urine collection devices  
and urine collection systems

This invention relates to a urine collection device and systems, particularly but not exclusively, for use by females. In particular and again not  
5 exclusively, the urine collection device is configured such that it can be connected to a negative air pressure, such as by means of a vacuum pump and urine can be collected when the user is in a number of positions, including both the supine and reclining position.

Devices for the collection of urine from female patients who are bedridden  
10 are known. Such devices often involve catheters that have to be inserted within the urethra of the patient, which in itself can be an uncomfortable procedure. Further, catheters often form a site where bacteria can accumulate which may result in the infection of the urinary tract and possibly the bladder thereby leading to complications in the treatment of an individual.

15 It is known to use specially shaped funnels, which are shaped to the contours of the female genital region and these collect and conduct urine away from the user's body. Such urinary funnels are disclosed in EP 464575 and W0 90/13280 and GB 2362577. However, some known funnels used in the reclined or supine positions do not form an adequate seal between the user and also  
20 "puddling" of urine within the device can occur. Consequently, known urine collection devices are prone to leakage due to the backflow of urine contained that has collected within the device, which has the disadvantage that both the user and bed linen may become soiled by leaked urine. Further, known devices are not designed for use when the patient is in a number of positions for

example lying down or sitting in a reclining position.

An aim of the present invention is to provide a hygienic and simple to use urine collection device that avoids leakage of urine from the device and which can be used when the user is in a number of positions.

5        According to a first aspect of the invention, there is provided a urine collection device comprising a funnel having a front wall positionable towards the pubic bone area of the user, side walls being positionable either side of the area of the user's body from which urine is expelled and a bottom wall, positionable towards the rear of the user, the upper edge of the front and forward parts of the side walls forming an opening for the funnel which extends around the area of  
10       the user's body from which urine is expelled, the funnel also having an outlet by which urine can be removed from the urine collection device, wherein the opening for the funnel leads to a urine receiving area formed by the front wall and forward parts of the side walls of the urine collection device, said urine  
15       receiving area leading to a urine collection reservoir formed by the bottom wall and rearward parts of the side walls of the urine collection device, said urine collection reservoir having a back wall extending from the opening of the funnel in the vicinity of the perineum of the user towards the bottom wall so that the urine collection reservoir is provided as a substantially closed chamber, which  
20       receives urine indirectly from the user via the urine receiving area, said urine collection reservoir leading to the outlet so that urine can be removed from the funnel.

Preferably, the opening of the funnel is contoured such that it generally has an arcuate shape with front part and rear parts of the opening being raised

in comparison with the side walls of the opening, said raised parts forming a two point axis of contact with the user's body. The whole of the circumference of the opening is in contact with the user's body but the two point axis defines a line in the x-x axis of contact with the user.

5           It is desirable that the opening of the funnel includes a lip curling towards the inside of the funnel. This lip forms a gutter that assists in directing urine towards the urine-collection reservoir.

          Preferably, the lip has an irregular profile with there being a greater degree of lip at the front part of the opening than at the rear part of the opening.

10           Ideally, there is no lip towards the rear of the opening in proximity to the perineum. By having the lipped graduated gutter arrangement, urine generally flowing through the device, i.e. urine which is not being propelled into the receiving area is caused to be deflected back into the device and downwards so that it is directed towards the collection reservoir and the outlet end; thereby  
15           avoiding leakage. It may be that the lip of the device is formed of a softer material than the main body of the device so that there is some give in the lip to allow deformation to form a seal with the body of the user. Advantageously, the lip forms part of a detachable upper part of the device, the lower part being of more rigid material such that where multiple devices are used in e.g. hospitals,  
20           respective upper and lower parts of the device can be interchangeable.

          In a preferred arrangement, the back wall of the urine collection reservoir is sloped away from the two-point axis of contact, in a direction away from the user's body.

          Advantageously, the back wall is at an angle of between 120° and 160°

and more preferably at an angle of 130-150° from a plane formed by the two-point axis.

Ideally, the back wall is at an angle of about 146° from a plane formed by the two-point axis of contact.

5 It is preferred that the bottom wall of the urine collection device is at an angle of about 106° from the back wall of the device but this angle may vary by 15° either side of this value.

Advantageously, the outlet has an opening leading from the urine collection reservoir, which is positioned such that said opening is directed  
10 towards an area of the device where the back wall and the bottom wall of the urine collection reservoir meet. The outlet may be formed as a tube within the body of the device with a wall of the tube merging into the bottom wall of the urine collection device. The use of a tube within the urine collection device itself to form the outlet allows for a weir to be formed so that urine in the collection  
15 reservoir is directed to flow towards the opening for the outlet. This allows for controlled flow of urine from the device without splashing or back flow of urine to the opening for the device.

It is envisaged the urine collection device includes one or more weirs on inner sidewalls of the funnel to control flow of urine within said device.

20 Preferably, at least one of the weirs is positioned before the opening of the outlet leading from the device.

It is also envisaged that there may be weirs in proximity to the opening of the urine collection device, said weirs being in contact with the patient's body so that urine may be more efficiently directed towards the inner surface of the

funnel. The use of said weirs has the advantage that they assist in directing the flow of urine from the patient into the body of the urine collection device.

Preferably, the weirs each have a curved surface. By having a curved surface, this assists in preventing the weirs from being deflected counter to the flow of urine due to the pressure of urine within the device. If deflection is avoided, there is a reduction in splashing of urine. This assists in encouraging cross flow of urine back into the body of the device and prevents any downward flow of urine from the device to the perineum and ultimately down the legs of the user and possibly onto the nursing staff.

It is preferred that the outlet for the funnel can be connected to a tube of about 8 millimetres in order to direct urine from the funnel at a flow rate of about 60 millilitres per second.

Preferably the capacity of the collection reservoir of the funnel is at least 20 millilitres when being used in a supine position to avoid the risk of leakage.

Advantageously, the front wall of the funnel, which forms the front part of the urine-receiving reservoir, is provided as a smooth concave contour so that urine is deflected towards the urine collection reservoir and then to the outlet. The concave surface acts as a deflector for a urine stream and so the flow is controlled such that it may be directed over the surfaces of any weir present and into the body of the reservoir. The curved surfaces of the or each weir also aid in controlling flow thereby reducing the risk of leakage or splash back of urine. Also, by having a concave front face, there is the avoidance of turbulence, which could otherwise create a fluid/air mix that reduces the effectiveness of drainage from the funnel.



Preferably the urine collection device has a hand locating area on the walls of the device forming the urine receiving area. The hand locating area may be provided by visual or tactile areas that the user can locate so that they know when they are holding the urine collection device in the most appropriate orientation for use, whereby the user's hand is directed to be applied in the correct plane to pull the part of the device which contacts the perineum into that area, thereby avoiding having a gap between the urine collection device and the user.

It is envisaged that the funnel may include one or more air inlet apertures.

Preferably, a single air aperture is provided in the back wall of the funnel immediately above the urine collection reservoir, the opening of the aperture leading to a tube extending through the back wall of the funnel in the urine receiving area in a generally upright direction and leading to an opening on the outside of the funnel, which opening may preferably be surrounded by finger guards on the outside of the device so as to prevent accidental blockage of air into the device. The or each aperture may be in the walls of the part of the device forming the urine-receiving reservoir. It is envisaged that the or each aperture is valved, such as by means of a one-use foam valve. The valved arrangement may allow for pressure within the urine collection device to be regulated if urine is being removed from the device using a pump. Preferably, the valves are self-regulating in that when a certain negative pressure is reached within the device, then the valves are caused to operate. The valves operate by allowing air into the urine collection device before and during urination and this also stops negative pressure from the pump building up, which may harm a user

of the funnel. As urination occurs, which may be detected by a sensor within the valve or the body of the device, the valve or valves are caused to close so that leakage from the device is prevented. The change over from negative to atmospheric pressure may cause also the valves to operate. Also, negative  
5 pressure can build up so that urine can be removed from the device.

The positioning of the angle of the walls of the various parts of the urine collection part are important in that by having walls that have defined angles relative to one another and curved surfaces, urine is caused to flow through the device at an optimum rate whilst avoiding excessive turbulence that could  
10 otherwise disrupt the flow dynamics of the urine within the device.

Further, by having an outlet that is offset from the opening of the funnel, urine flow is fed to the outlet in a controlled manner rather than being able to directly reach the outlet as in known devices. Urine is instead allowed to pool at the lowest point of the urine collection, which is formed by the urine collection  
15 reservoir, thereby leading urine to the mouth of the outlet part so that urine can be sucked away. Further, by having a series of angles for the urine collection device, the device can be used when the patient is both in the sitting and supine positions. This is because the back face and bottom face are at an angle so that urine is constantly being removed from the device at peak flow rates, via the  
20 outlet a peak flow rate being typically 60 millilitres per second, whilst at the same time avoiding leakage.

According to a second aspect of the invention, there is provided a urine collection apparatus comprising a funnel having a front wall positionable towards the pubic bone area of the user, side walls being positionable either side of the

of the area of the user's body from which urine is expelled and a rear wall, positionable towards the perineum area of the user, the upper edge of the front and forward parts of the side walls forming an opening for the funnel which extends around the area of the user's body from which urine is expelled, the  
5 funnel also having an outlet by which urine can be removed from the urine collection device, wherein the opening for the funnel leads to a urine receiving area formed by the front wall and forward parts of the side walls of the urine collection device, said urine receiving area leading to a urine collection reservoir formed of the rear wall and rearward parts of the side walls of the urine  
10 collection device, said urine collection reservoir having an upper wall extending from the opening of the funnel towards the rear wall so that the urine collection reservoir is provided as a substantially closed chamber which receives urine indirectly from the user via the urine receiving reservoir, said urine collection reservoir leading to the outlet so that urine can be removed from the funnel, the  
15 outlet being connected to a tube leading to a suction pump by which urine from the urine collection device can be removed to a urine collection chamber.

Preferably the funnel includes a weir to prevent or inhibit backflow of urine away from the direction of suction.

Conveniently, a valve is incorporated within the apparatus such that urine  
20 exiting from the funnel cannot flow back under gravity when the suction pump is deactivated.

It is envisaged that the pump is a linear diaphragm pump. Linear diaphragm pumps have the advantage that they can achieve high flow rates required to meet the initial instantaneous flow rate that occurs when a person is

urinating, with the added advantage of being small, lightweight and easily portable and also being relatively quiet.

Advantageously, the pump is a compressor that is self limiting in terms of negative pressure that can be produced. This provides an inherent safety feature in that it avoids the production of unsafe vacuum within the funnel which can harm the user of the urine collection device.

Advantageously, the pump includes a silencer and/or a carbon filter to reduce odours

Typically, the suction pump leads to a collection vessel which is a sealed airtight vessel, which can be depressurised by the compressor to a negative pressure of about 270 millibars.

It is preferred that the pump includes access to a check program to ensure correct operation and connection of the pump to the urine collection device and/or the urine collection chamber. The check program may be preceded by an indication of whether the pump is on or off and this can be provided by a visual indication on a display or an audible warning. Once the pump is judged to be operating correctly, an indication may be given to the user that they can start using the pump with the urine collection device.

Preferably, a test program is provided which prompts the user to check that the arrangement is operating properly after the pump is switched off. An example of this is where the pump has been switched off to empty the urine collection chamber. An indicator is activated after the chamber has been emptied to prompt the user to run the check program again. The test program is controlled as a result of receiving signals from various parts of the pump

arrangement. A sensor may be associated with the container to check that it has been properly connected to tubing associated with the pump.

Further tubing leading to and from the pump can also include sensors at one or more points to receive information about blockages or power leaks in the pump system.

It is preferred that pressure checks are performed by the pump being caused to evacuate the pump arrangement to set a negative pressure and a check is made to see if this pressure is reached and held for a predefined period of time. If the check result is a negative result, the user will be prompted to check the system to ensure that tubing and connections between the tubing and components such as the container for the urine are secure.

Advantageously there is a hydrophobic filter membrane between the collection vessel and the pump to prevent any potential ingress of urine into the pump, which could otherwise have major health and safety implications. Further, the filter membrane assists in preventing ingress of bacteria.

It is envisaged that the collecting vessel may be calibrated to measure the amount of urine the patient is releasing so that flow rates of fluid through the body can be monitored.

Advantageously, the collection chamber includes a disposable bag having a tap at the bottom for emptying urine from the bag. This allows the bag to be used for a given a number of times, much like catheter bags, which are periodically drained. In a preferred arrangement, the collection chamber is associated with a sensor which can provide a signal for an indicator to inform a user when the bag within the collection chamber is full or has reached a certain

fill limit. Further, the collection chamber may have a sensor that can calibrate the flow rate of urine over a particular period of time to monitor whether a patient is producing urine at an appropriate amount relative to their fluid intake. By measuring flow rates, conditions such as oedema or urinary blockages may be detected.

In a preferred arrangement, the pump is provided as a portable device. It is envisaged that when the pump is portable, said pump is provided as a separate unit attachable to a docking station that can also accommodate the urine collection chamber. It is envisaged that the docking station is connectable to an external power source such as the mains electricity supply. However the pump may include its own integral power supply such as a rechargeable battery pack.

According to a third aspect of the invention there is provided a urine collection apparatus comprising a funnel for receiving urine, a pump arrangement for pumping urine the funnel and a collection device for receiving collected urine, said funnel having an outlet which is connected to tubing leading to the pump arrangement, wherein the pump arrangement includes sensors to detect parameters concerning itself, the tubing and the collection device and indicators to alert a user of the device whether defined parameters fall within or outside said defined parameters.

It is preferred that the pump arrangement includes a check program to monitor pressure within said urine collection arrangement.

Advantageously, a test program is provided with an indicator that prompts the user to check that the arrangement is switched on. Preferably, as well as

checking whether the arrangement is switched on, the user is prompted to check that all components are present and connected properly. The check may comprise visual indicators alerting the user of the stages in the check process to be taken. Alternatively, an audible prompt may be used to talk the user through the various stages in the check procedure.

Preferably, the check program includes means to indicate when the collection chamber has been detected as having been emptied, then the user should run the check program again. The test program is controlled as a result of receiving signals from various parts of the pump arrangement. A sensor may be associated with the container to check that it has been properly connected to tubing associated with the pump. Further tubing can also include sensors at one or more points to receive information about blockages or power leaks in the pump system.

It is preferred that pressure checks are performed by the pump being caused to evacuate the pump arrangement to set a negative pressure and a check is made to see if this pressure is reached and held for a predefined period of time. If the check results in a negative result being shown, the user will be prompted to check the system to ensure that tubing and connections between the tubing and components such as the container for the urine are secure.

Preferably, the pump is provided as a portable device, which can be docked with a base station adapted to receive said pump and a urine collection chamber.

It is envisaged that the pump includes its own power supply or it can be connected to a power supply provided by the base station or from mains

electricity.

According to a fourth aspect of the invention, there is provided a portable urine collection system for use with the urine collection devices described, the system including a system housing containing an electrically operable suction pump, a sealable container in or on the housing for containing a urine collection bag, the container having a lid and being connectable via tubing to a urine collection device, the container also being connectable to said pump such that when the lid is closed and the pump is activated air is drawn into the urine collection device and, via the urine collection bag container, to the pump, to thereby provide suction permitting urine to be drawn into the urine collection bag when the urine collection device is being used.

Conveniently, the housing is adapted to be releasably secured to an item of furniture such as a hospital bed and includes on an upper surface a drip tray and associated drip tray housing, the housing for the drip tray allowing the drip tray to be orientated in respectively opposite positions, the inside of the drip tray being shaped to permit the open end of the collection device to be releasably stored therein only in one of said orientations, thereby permitting either hand of e.g. a patient in the bed to pick up the urine collection device in its correct orientation, depending upon which side of the bed the system housing has been secured to and which way the drip tray is oriented.

The invention will now be described, by way of example only, with reference to the accompanying drawing figures in which:

Figure 1 shows in section a urine collection device according to the first aspect of the invention,



Figure 2a shows a urine collection device of Figure 1 in situ against the body of a user,

Figure 2b shows a front perspective view of the urine collection device of Figure 1,

5 Figure 3a shows the tilt angle of a urine collection device according to a first aspect, when a user is in a reclined sitting position,

Figure 3b shows the tilt angle of a urine collection device according to a first aspect, when a user is in a supine position,

10 Figure 4a shows weirs positioned on the inside part of a urine collection device according to another embodiment of the invention,

Figure 4b shows a view from above of the complete urine collection device of Figure 4a including weirs,

Figure 5 shows suction pump and associated apparatus to be used with a urine collection device,

15 Figure 6 shows a portable pump and associated apparatus to be used with a urine collection device according to another embodiment of the invention,

Figure 7 shows an alternative embodiment of urine collection device to that shown with reference to Figures 1 to 4,

20 Figure 8 shows a portable urine collection system incorporating the urine collection device of Figure 7, and

Figure 9 is an exploded view of the system shown in Figure 8.

Referring firstly to Figures 1 to 3, the urine collection device shown generally at 1 comprises a funnel body 2 having an open rim 3 defining a urine

inlet opening for the device 1. Upper rim 3 has an upper contact region F which contacts the pubic bone area of a user of the device, and a lower contact region R, which contacts the perineum area of the user. As is shown in Figure 1, between the upper contact region F and lower contact region R is a region U which is typically the area of the urine collection device 1 in proximity to the area of the user's body surrounding the urethra.

The funnel body 2 has a smoothly contoured, generally concave, inner front face 4 and an outer "pinched" surface which may be gripped by the hand of a user of the device.

The urine collection device shown generally at 1 comprises a funnel body 2 having an open upper rim 3 defining an opening for the device 1. Upper rim 3 has an upper contact region F, which contacts with the pubic bone area of the user and a lower contact region R that contacts with the perineum area of the user. Between the front region F and the rear region R there is a region U, which is typically the area of the urine collection device 1 which is in proximity to the area of the user's body surrounding the urethra. The funnel body 2 has a contoured outer front face 7 leading from contact point F to form a bowed concave area 8, which is the typical region of where a user holds the urine collection device. The area forms the urine receiving area of the urine collection device and is the part of the device where the urine directly enters the device via the opening 3. The front curved area 7 leading to 8 forms a contoured 'S' curve leading towards outlet tube 9. The outlet tube 9 leads from an extension of the urine collection device 1 which extends from the rear of the opening 3 beyond the plane of contact point R to form the extension that provides a urine collection

reservoir 10 for the device. This urine collection reservoir is provided as a closed chamber that directs urine to the urine collection reservoir prior to it passing to outlet tube 9. The chamber includes a back wall 11 and bottom wall 12, which are angled with respect to one another thereby providing the collection chamber with a substantially rectilinear shape to provide the urine collection reservoir 10. Area 3a provides a lip for the opening leading to a weir.

Figure 2a shows urine collection device 1 in situ against a user of the device. The urethra of the user is shown as U and the front and rear contact points F, R are where the urine collection device contacts with the user's body. Edge 3 will also contact with the body. The labia majora 13a will seat outside the walls of the opening 3, forming a seal around the top of the opening. The labia minora 13b will be positioned within the device and can protrude up to about 18 mm within the device, the labia minora 13b being bounded by opening 3. The contact points F and R provide an axis running between lines x and x of the user's body. The back wall 11 is steeply angled relative to the axis x-x. Typically this angle is about  $146^{\circ}$  but as mentioned the angle may be  $130 - 160^{\circ}$ . If the angle is much greater, then the back wall 11 of the collection device 1 would press against the buttocks of the user making the device difficult to use because it does not seal with the user and also there is the possibility that the device would be knocked from position, thereby causing leakage. Back wall 11 is angled relative to bottom wall 12 and the typical angle between these walls is about  $106^{\circ}$  with a range being  $90 - 120^{\circ}$ . By providing such an angle, a urine collection reservoir is formed such that urine is caused to pool in the lowest part of the urine collection device, whether the user is sitting or lying down. Urine is

directed from the urine receiving area formed by curved face 8 towards the urine collection reservoir 10. This allows the urine to pool so it may be siphoned off rather than being directed back towards the opening 3 where leakage may occur. The opening to the outlet 9 is in proximity to the angled portion 14, where back wall 11 and bottom wall 12 meet. By having the opening to the outlet positioned in proximity to this angled portion, controlled flow of urine from and within the device may be facilitated.

Figure 2b is a perspective view from above of a urine collection device according to the invention showing the opening 3 front part F rear part R and urine collection reservoir 10. It can be seen that the urine collection reservoir is offset from opening 3, rather than being positioned directly under it.

Figures 3a and 3b respectively show the position of the urine collection device when a user is in a reclined sitting position, which is usually when a patient is propped up in bed by several pillows, and when a user is lying down in the supine position. As shown in Figure 3a, when a user is reclining, typically the device is held at about  $100^\circ$  to the horizontal relative to an axis coincident with contact points F and R.

Figure 3b shows the device when it would be used when a user is in the supine position, when typically, the corresponding angle to the horizontal is about  $125^\circ$ , which is a much steeper angle than when the user is reclining. However, from both positions, it can be seen that the urine collection reservoir 10 is always maintained as the lowest part of the device and it is here that urine is held prior to it being removed through opening 9a of outlet pipe 9.

Figure 4a is a cut away view of the rear part of the urine collecting device

having vanes 15 on the internal surface of the device. These vanes provide weirs which are angled such that urine would be directed towards collection point 10 and ultimately to outlet 9.

Figure 4b shows the view from above of the vanes 15 in situ relative to opening 3.

Figure 5 shows how a pump may be used with a urine collection device of the invention. This pump may be used with a urine collection device as previously described or with other types of urine collection devices. It is preferred that the pump is a linear diaphragm pump, typically having a specification of 230 volts 50/60 Hertz frequency and a maximum pressure of 5.5 psi with a maximum of 50 millimetres hd2 under a 50 millimetres hg is used. Typical maximum power is 27 watts with a free airflow of 40 litres per minute.

A urine collection device 1 is attached to a tube 16, having an inlet 17 for attachment to the urine collection device 1, on the end of which tube 16 may be a cap to close off the tube if needs be. The tube is preferably 8 millimetres in diameter and a typical length of tube is around 1.8 metres. The end of the tube attachable to the pump interacts with an airtight seal 18 which controls the flow of urine into a collecting vessel 19. Typically the collection vessel is under negative pressure. The collecting vessel may include a disposable bag 20, which stores urine 21, the collectable bag can have a outlet valve 22 for siphoning off urine when it gets to a particular level. This may be detected by a sensor 23 which typically is a level sensor located adjacent to the collecting vessel and senses when the bag fluid level has reached a predefined level. The pump may include a cut off switch which will not allow the pump to restart until

which will not allow the pump to restart until the bag 20 has been emptied. It is envisaged that the pump housing includes an indicator 24 which can be activated by the sensor to give an audible and/or visual alarm when the bag needs to be emptied. The indicator can include an on off switch as well as an indicator to show that the pump 25 is running at required parameters. The indicator may also include a prompt for the operator to run a test programme. It is envisaged that if a test programme is not run successfully, the pump cannot be used. The test programme tests that the bag has been changed and that there are no air leaks in the system or blockages which could affect the successful use of the equipment by the user. The test system works by evacuating the system to set a negative pressure and checking that this pressure is reached and maintained. In order to do this, the operator must close a clamp on the tube and then press the test programme button. If the test is successful, indication will be shown on the display 24 which will then prompt the operator to check that the collecting vessel and bag are connected correctly and if there is still no operation of the pump, then the user would be prompted to fit another collection bag. In order to reduce odours etc, there is charcoal filter 26 which may be incorporated or provided separately from a silencer. Such arrangements make the device more pleasant to use in that it reduces odour and maintains a quiet environment when the pump is being used.

The arrangement shown in Figure 5 is a one to one arrangement where a mains powered single pump is used with an individual urine collection device. Figure 6 shows a portable urine collection device in accordance with another embodiment of the invention. As before, a tube 16 attachable to a urine

This base may be connected by an electrical power source via electric plug 28. This base provides a base station onto which a portable pump arrangement 29 can be seated. This arrangement has a pump 25 and indicator 24 and a carry handle 30. The pump arrangement 29 is docked onto the base station and connections are made with tubing for air to be sucked through via the pump 25. The power supply between the base station and the portable pump is provided by electric connector point 32. Tests will be made using the indicator panel 24 to ensure that appropriate electrical connections have been made and that urine has been correctly connected so that the device will operate properly.

By providing a portable pump device 29 that may be transmitted between patients, there is a reduced risk of cross contamination and also a cost consideration that one pump can be provided by e.g. several patients on a ward. It is envisaged that the portable pump/control 29 unit can also contain a rechargeable battery pack so that the device does not necessarily have to be plugged into the main power supply. Further, by having parts that can be interconnected, some parts may be provided as disposable elements that can be replaced easily while other parts of the arrangement can be dismantled for sterilization when needs be.

Referring now to Figure 7, there is shown a perspective view of an alternative embodiment of urine collection device to that shown with reference to Figures 1 to 4 although it is of the same general internal shape. In this embodiment the funnel body is in two part form, an upper, resilient, part shown generally at 2a and a lower generally rigid, part shown at 2b, the upper part 2a typically being made of an elastomeric material, and the lower part 2b typically

being made of rigid plastics. With this arrangement, through the use of raised formations 33 extending circumferentially around the upper rim of the lower part 2b, being co-operable with correspondingly shaped apertures 34 extending circumferentially around the lower rim of the upper part 2a, the upper part 2a is detachable from the lower part 2b in this region. This has the advantage in that the upper part 2a may be replaced with either a new one, or even one of a different size and shape, and similarly the lower part 2b may be replaced as required.

In this embodiment of urine collection device, the urine exit tube 9, shown partially in broken outline, leads to an annular connector spigot 35 onto which may be push fitted the socket end of an adaptor fitted to the end of a flexible tube for removing urine from the urine collection device 1 in a manner to be described.

On the lower outside front wall of the lower part 2b of the funnel is mounted a small magnet 36 which can be used for ensuring that the funnel 1 is stored in a required position, again in a manner to be described.

Above the tube 9 in a generally upright orientation is an aperture 36, shown in broken outline forming one end of a generally upright tube 37, shown partially in outline leading from the inside of the funnel to the outside immediately below a roof portion 38 of a finger handle 39, having a central web 40. In order to protect the open, upper, end of the tube 37 from accidentally being blocked by a finger of a user of the device, a pair of planar finger guards 41 (only one of which is shown) are positioned on either side of the inlet tube 37 so that its inlet end 37a cannot be accidentally blocked from the ingress of air.



Referring now to Figures 8 and 9, there is shown a front perspective view of a complete portable urine collection system adapted to be releasably secured by e.g. hook formations, onto the side or end of a hospital bed. The system comprises a housing 42 containing a vacuum pump (not shown) and also a urine collection bag container 43, shown partially in broken outline; having a window 44 for visually inspecting via a suitable scale the level of liquid within a urine collection bag 55 (shown in Figure 9). The top end of the urine bag collection container 43 is closed by means of a lid 45 through which extends an elbow-shaped hollow spigot 46 onto the end of which is push fitted the end of a flexible urine collection tube 47, connected at its other end to the spigot 35 of the urine collection device 1a of Figure 7.

Also extending through the lid 45 is a tap member 48 through which air can flow from the inside of the container 43 to an outlet tube 49 connected at one end to the outlet end of the tap 48 and at its other to the inlet end of a conduit (not shown) on the outside of the housing 42 leading to the pump, to thereby permit air to be drawn through the tap 48 and outlet tube 49 into the pump.

The urine collection apparatus 1a is housed within a tray 50 of symmetrical outer shape such that it can be received within correspondingly shaped cradle members 51, 52 in two orientations, each opposite to the other.

The inside surface 53 is, however, shaped to closely follow the outer contours of the urine collection device 1a so that the latter may be orientated in the position shown whether or not the housing 42 is on e.g. the left or right hand side of a hospital bed, the advantage being that for a bedridden user of the

device 1a it is always orientated correctly.

As will be seen more clearly with reference to the exploded view of Figure 9, the tray 50 has a flanged upper edge 54 which extends around its entire periphery so that when the tray 50 is received between the cradles 51, 52 it may be orientated in opposite directions or, put another way, it may retain the same position as shown even though the housing of the urine collection system is twisted vertically through 180°, thereby permitting use of the apparatus on either side of e.g. a hospital bed. In turn, when not in use, the urine collection device 1A may be simply retained within the interior of the tray 50 and may e.g. be locked in place by virtue of the magnet 36 resting against a metallic object (not shown) embedded within the tray 50.

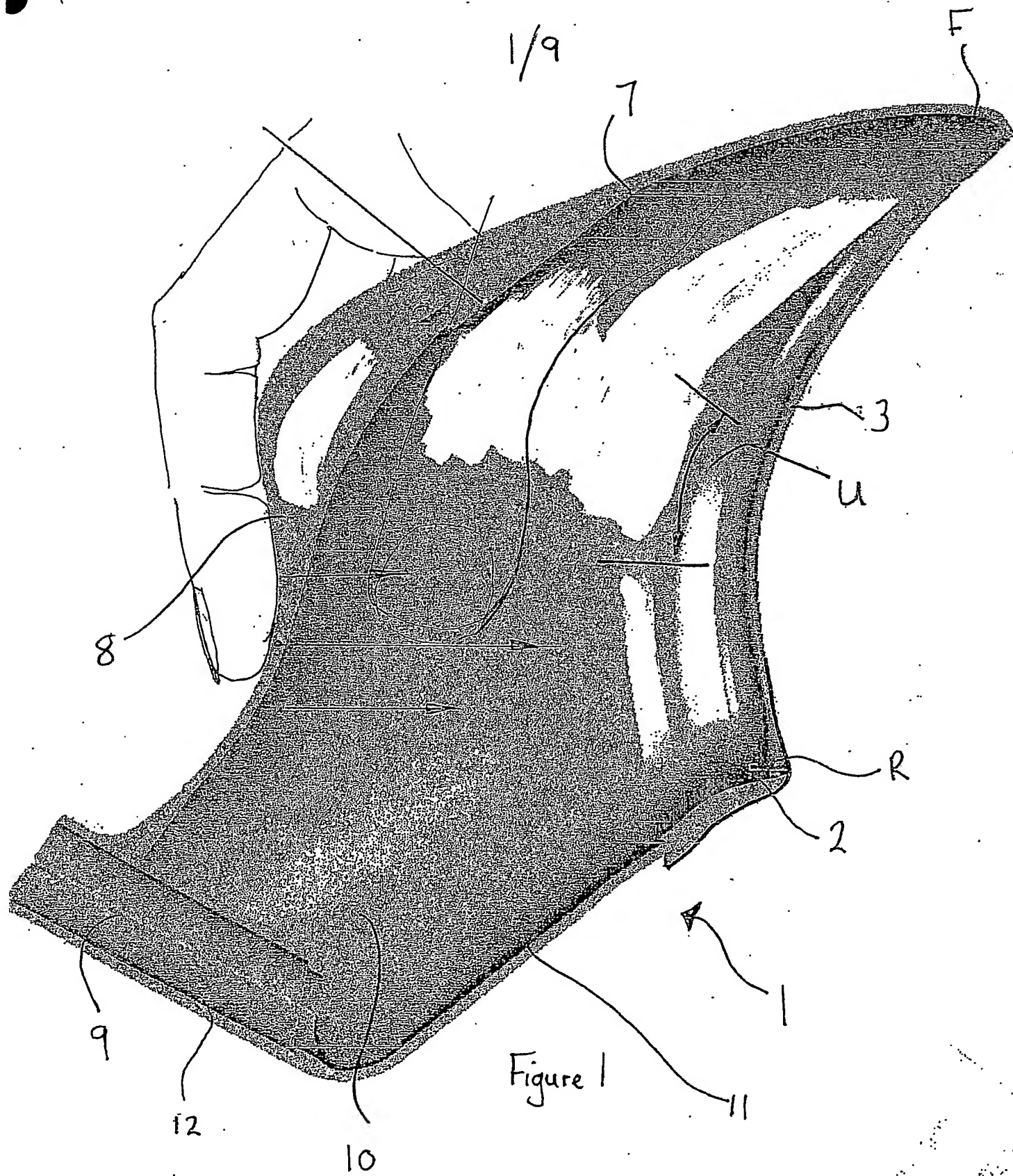
The cap 45 releasably connects with a urine collection bag 55 (shown partially in outline) which bag may be reusable or, preferably, disposable, and by virtue of the portability of the system, when the bag is full the housing 42 may simply be lifted and taken to e.g. a sluice area to prevent any splashes along the way and then the lid 45 released to allow the bag 55 to be removed therefrom. Following this, a new bag may be fitted and e.g. the tray and urine collection device 1a rinsed out, washed, sterilised or even partially or wholly replaced as required.

Although the urine collection device and system of the invention in its various aspects is particularly adapted to be used by females, it is envisaged that the device itself could be used by males having a short urethra or possibly males that are undergoing gender realignment surgery. It is envisaged that such a device, like the present device will have a collection reservoir formed of

substantially closed chamber extending from a region in proximity to the perineum towards the buttocks.

It is to be understood that the above detailed description are embodiments of the invention and are provided by way of example only.

5 Various details in the design and construction of devices described may be modified without departing from the true spirit and scope of the invention.



2/9

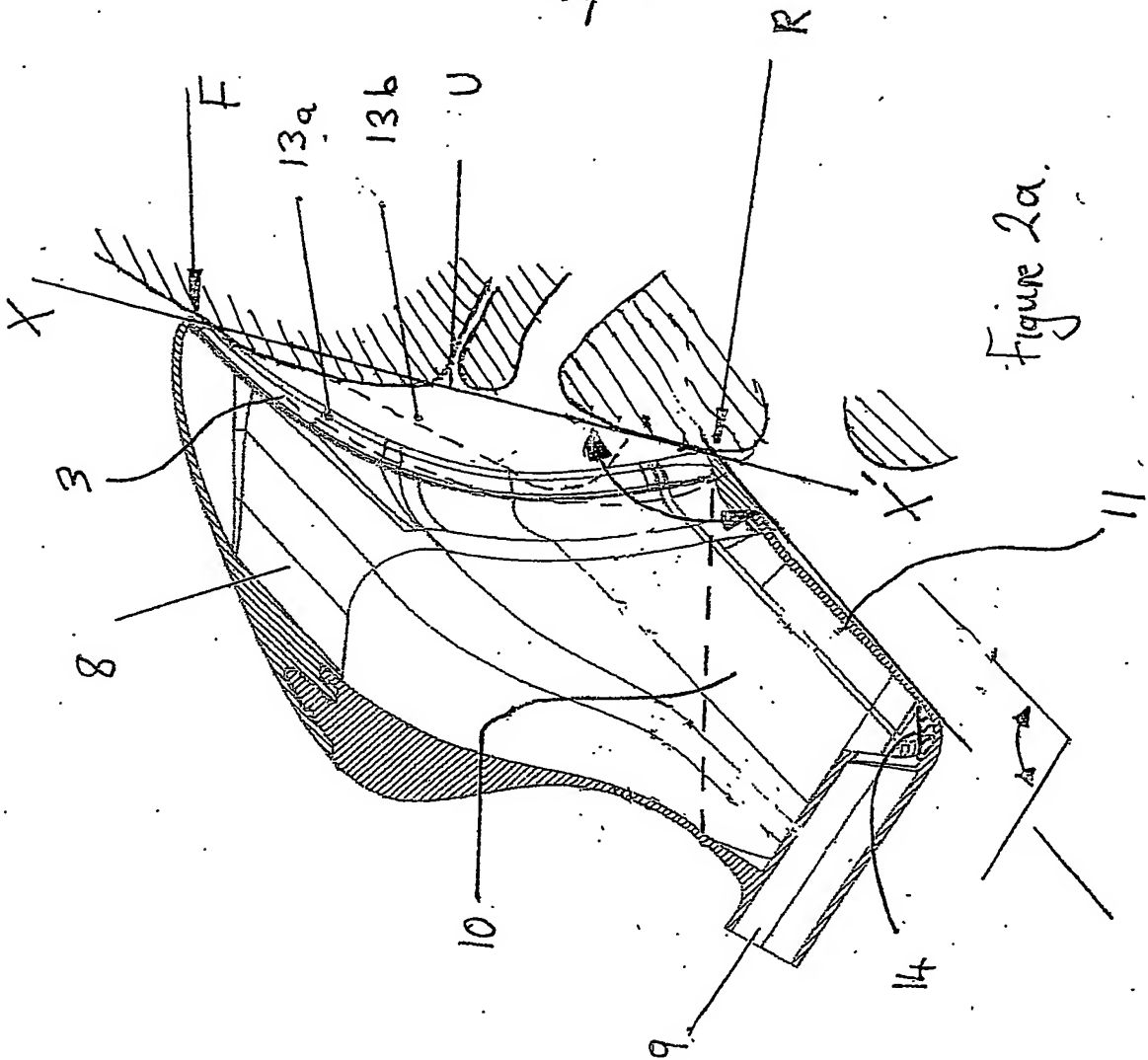


Figure 2a.

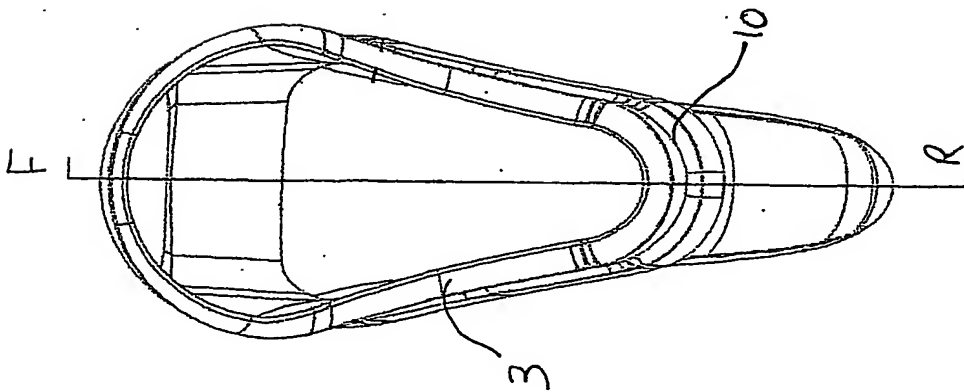


Figure 2b

3/9

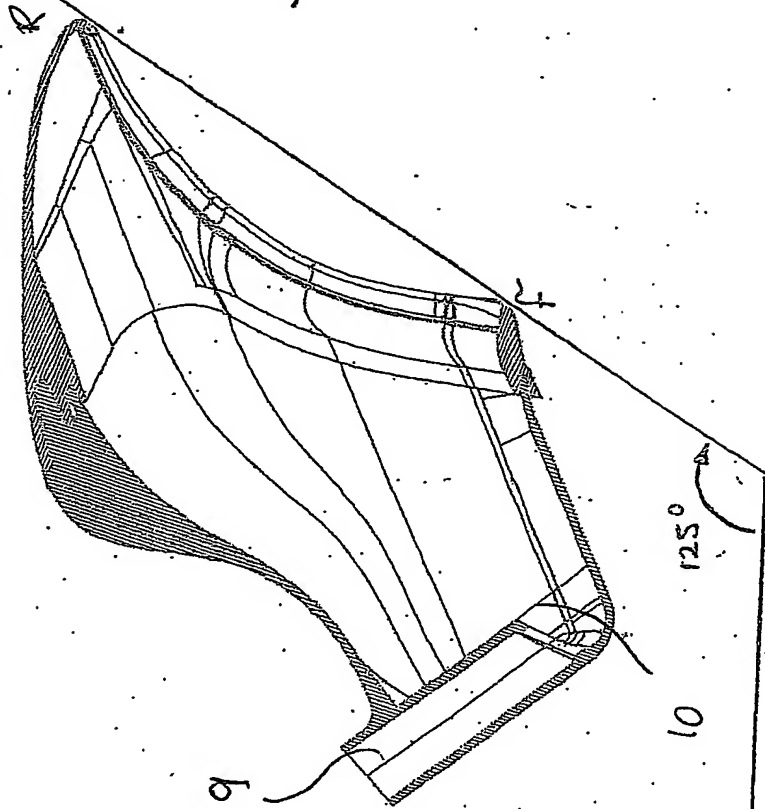


Figure 3b

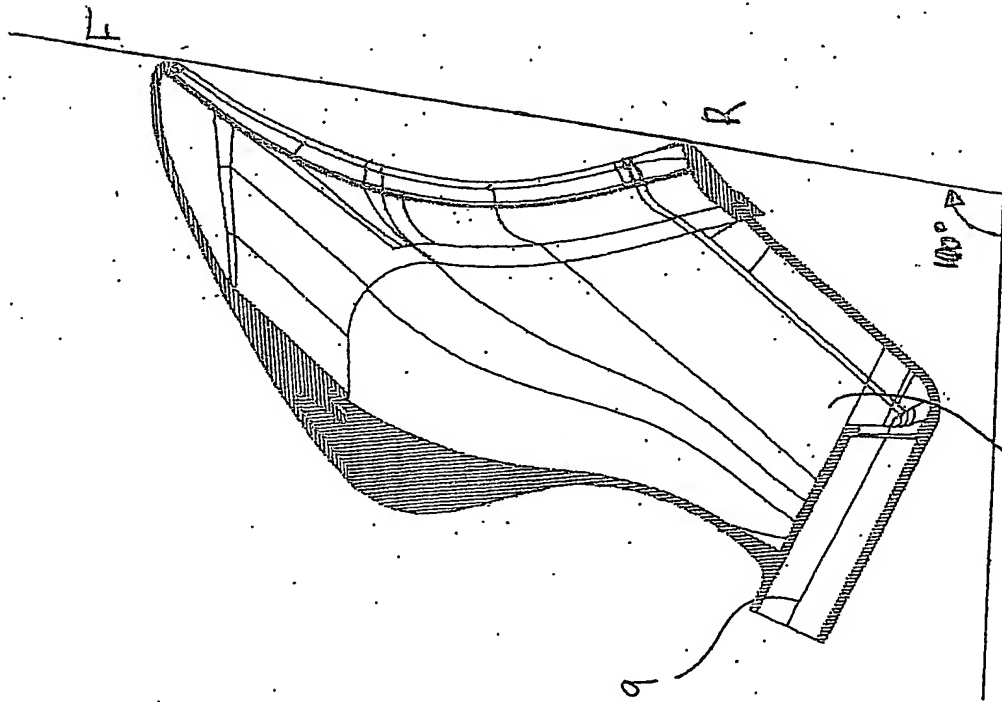


Figure 3a

4/9

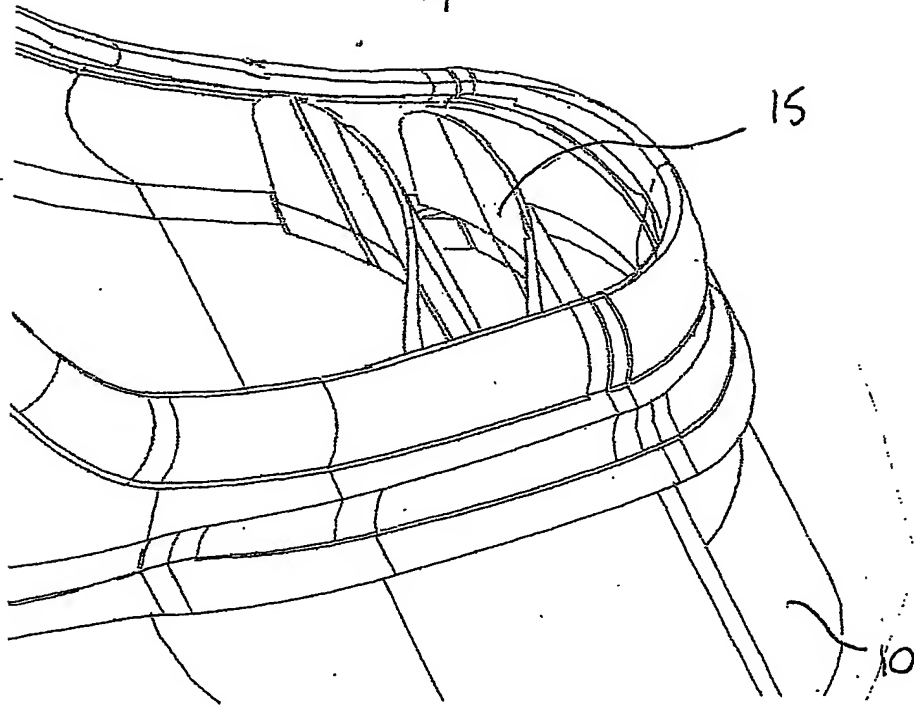


Figure 4a

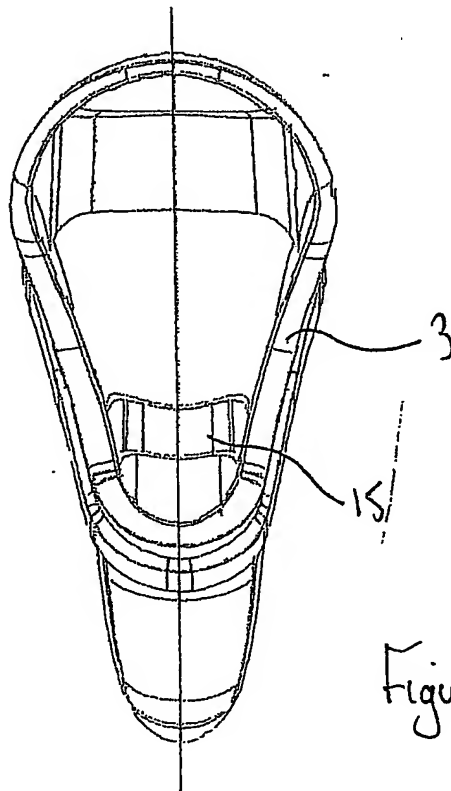


Figure 4b

5/9

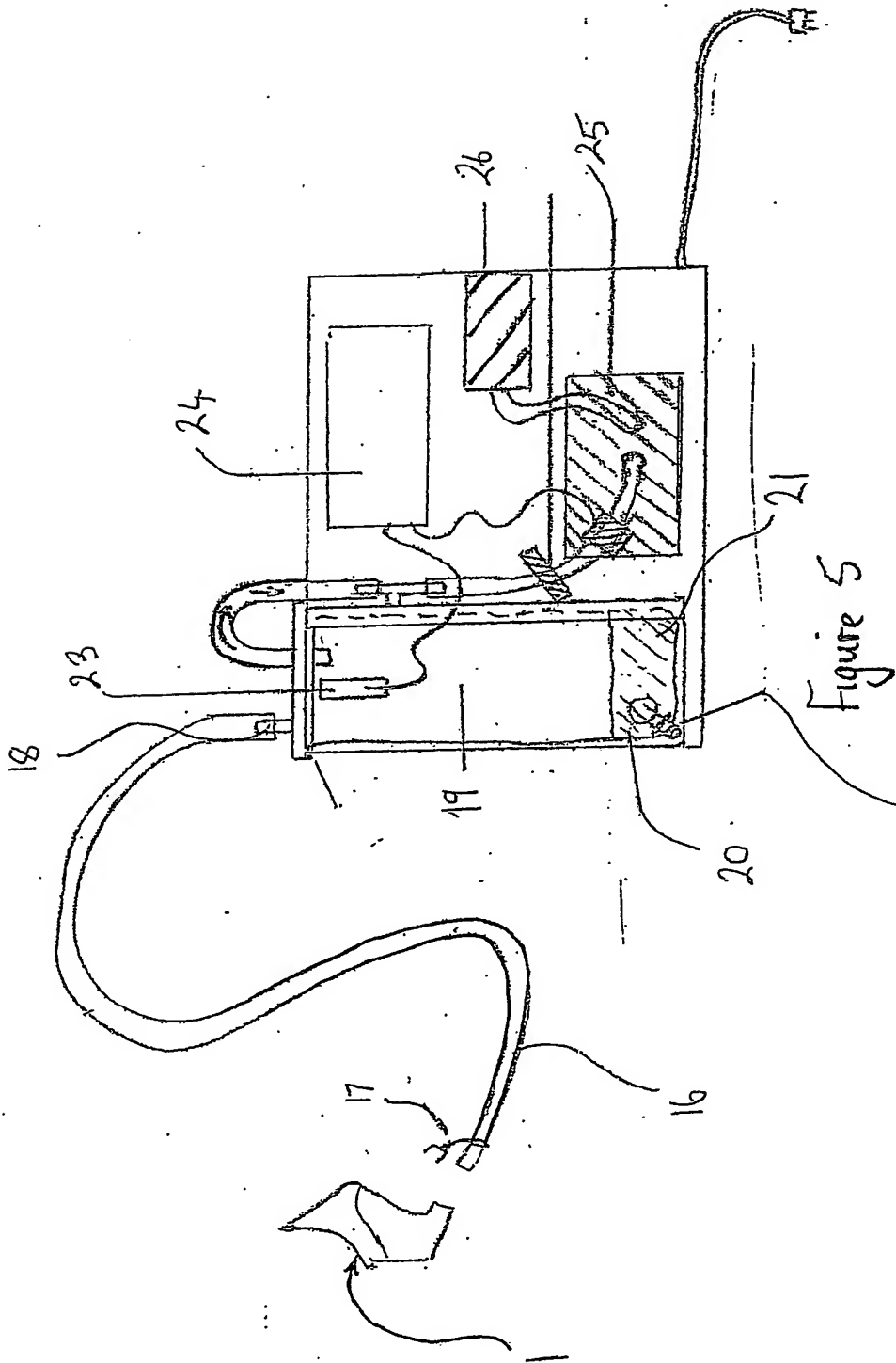
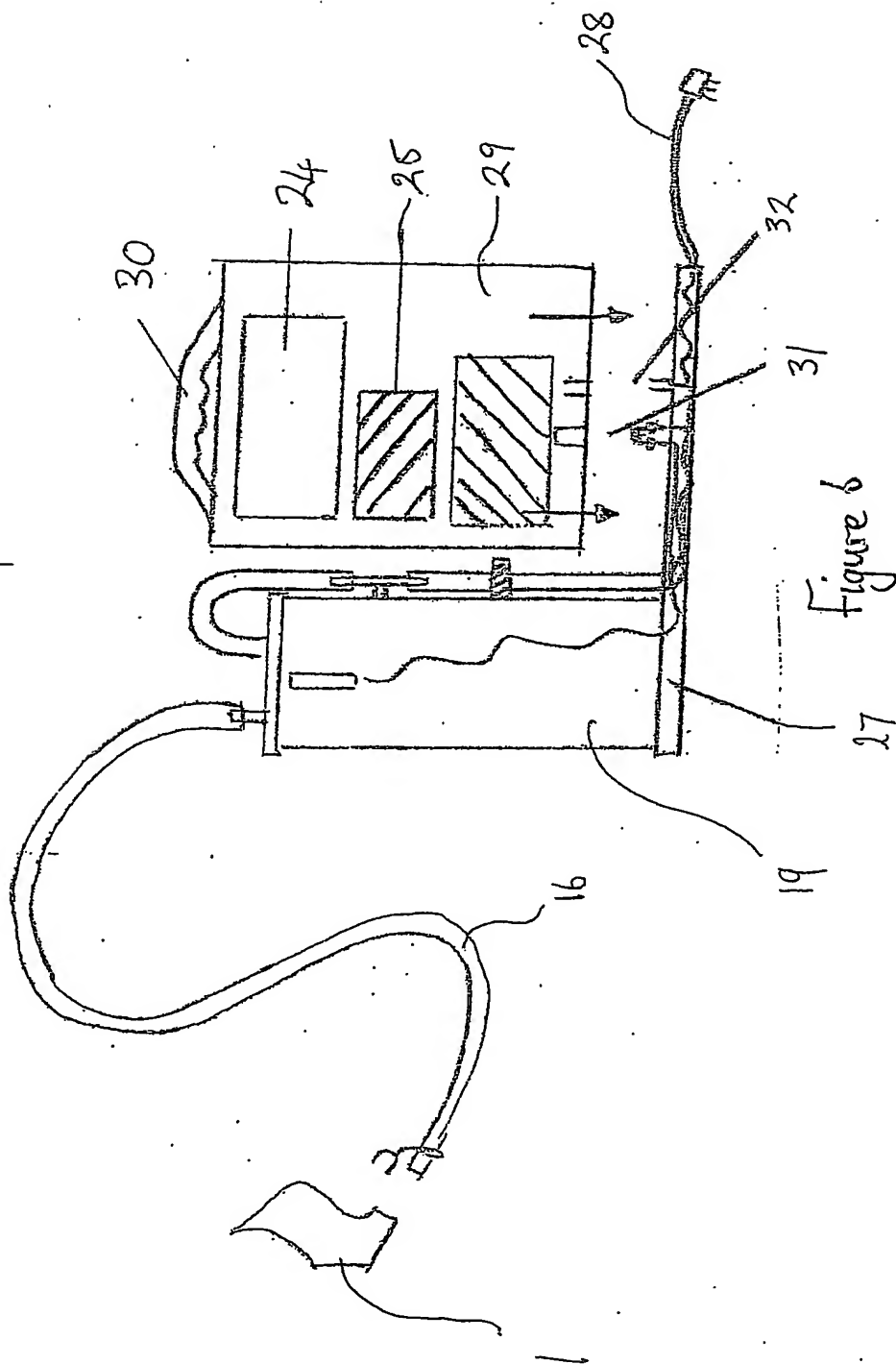


Figure 5

22



6/9



7/9

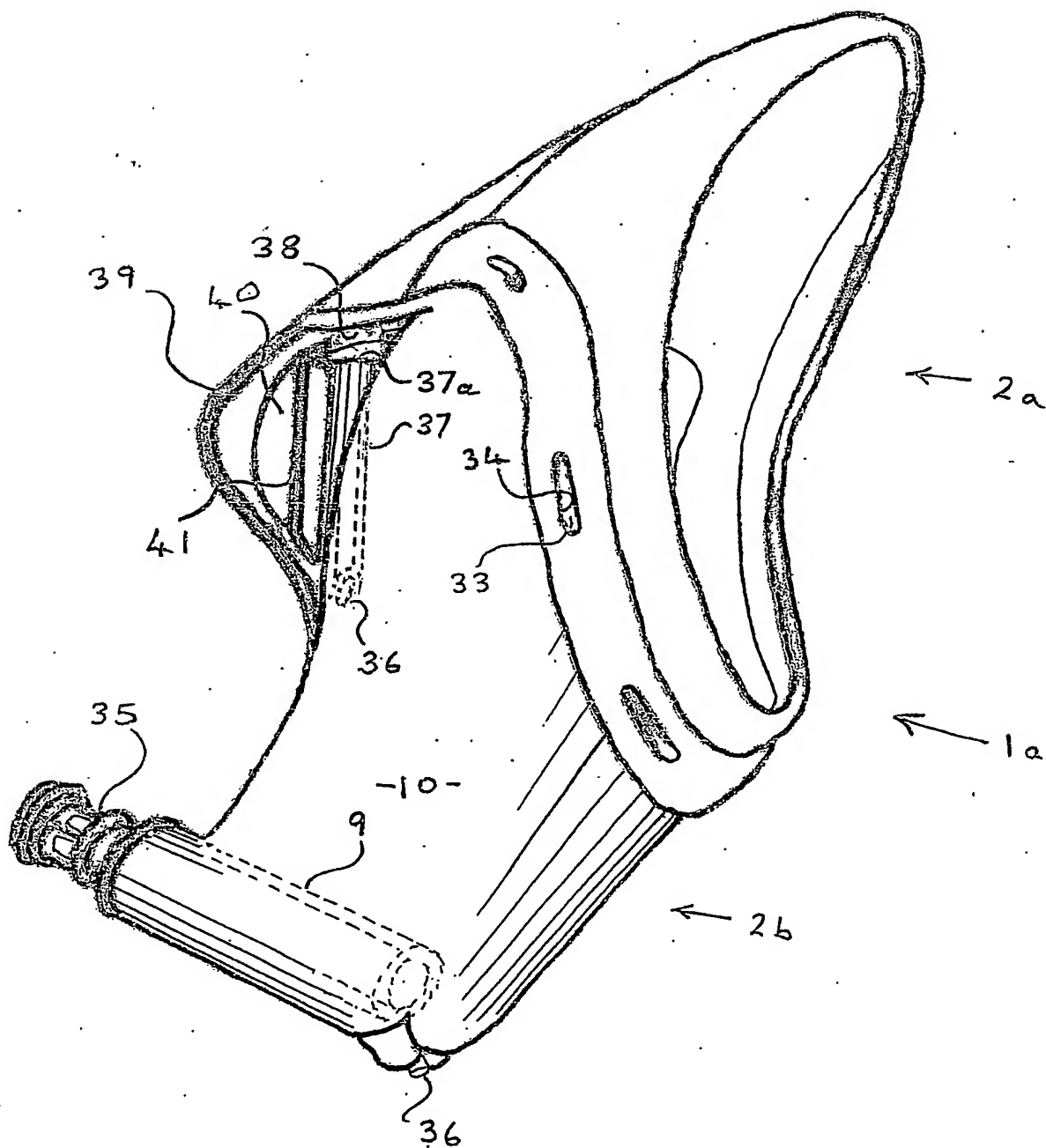


FIGURE 7

8/9

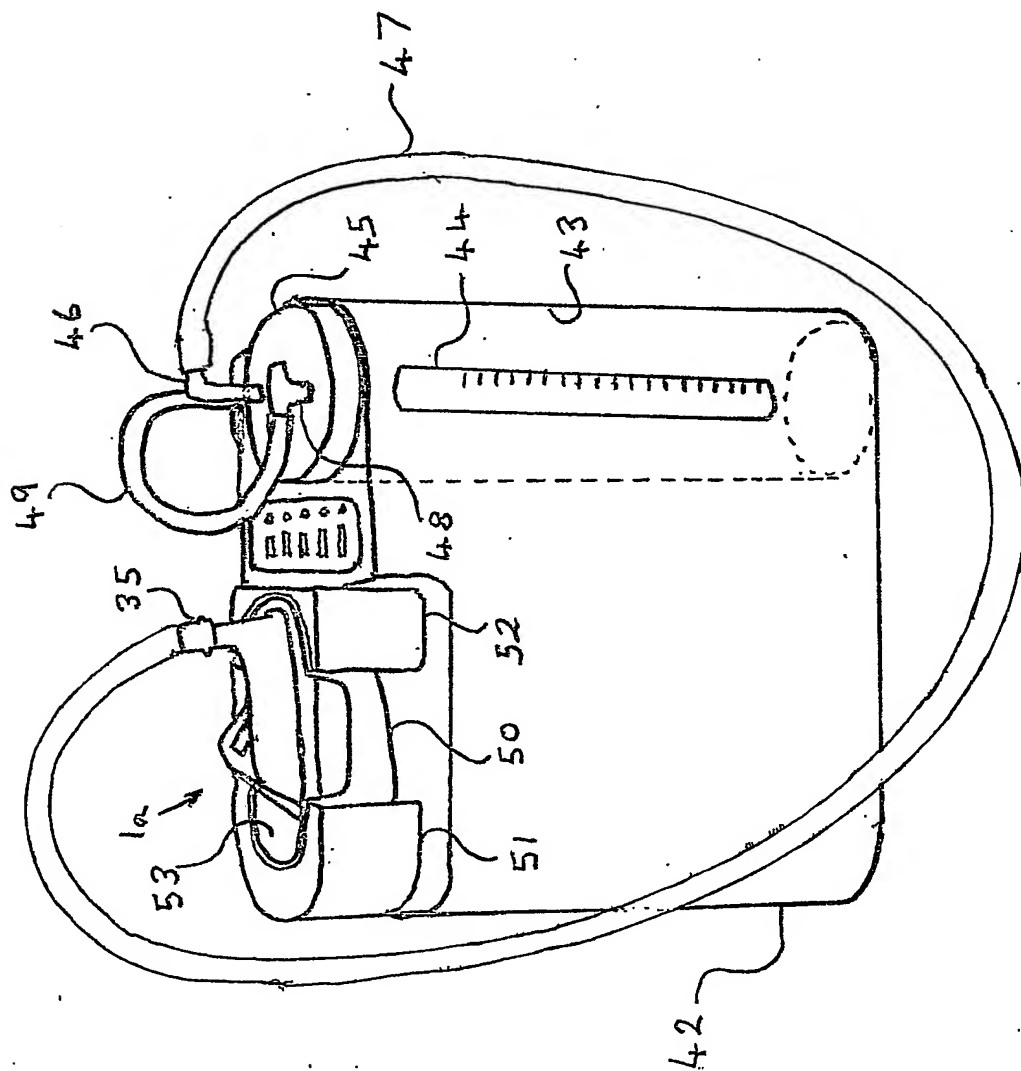


FIGURE 8

9/9

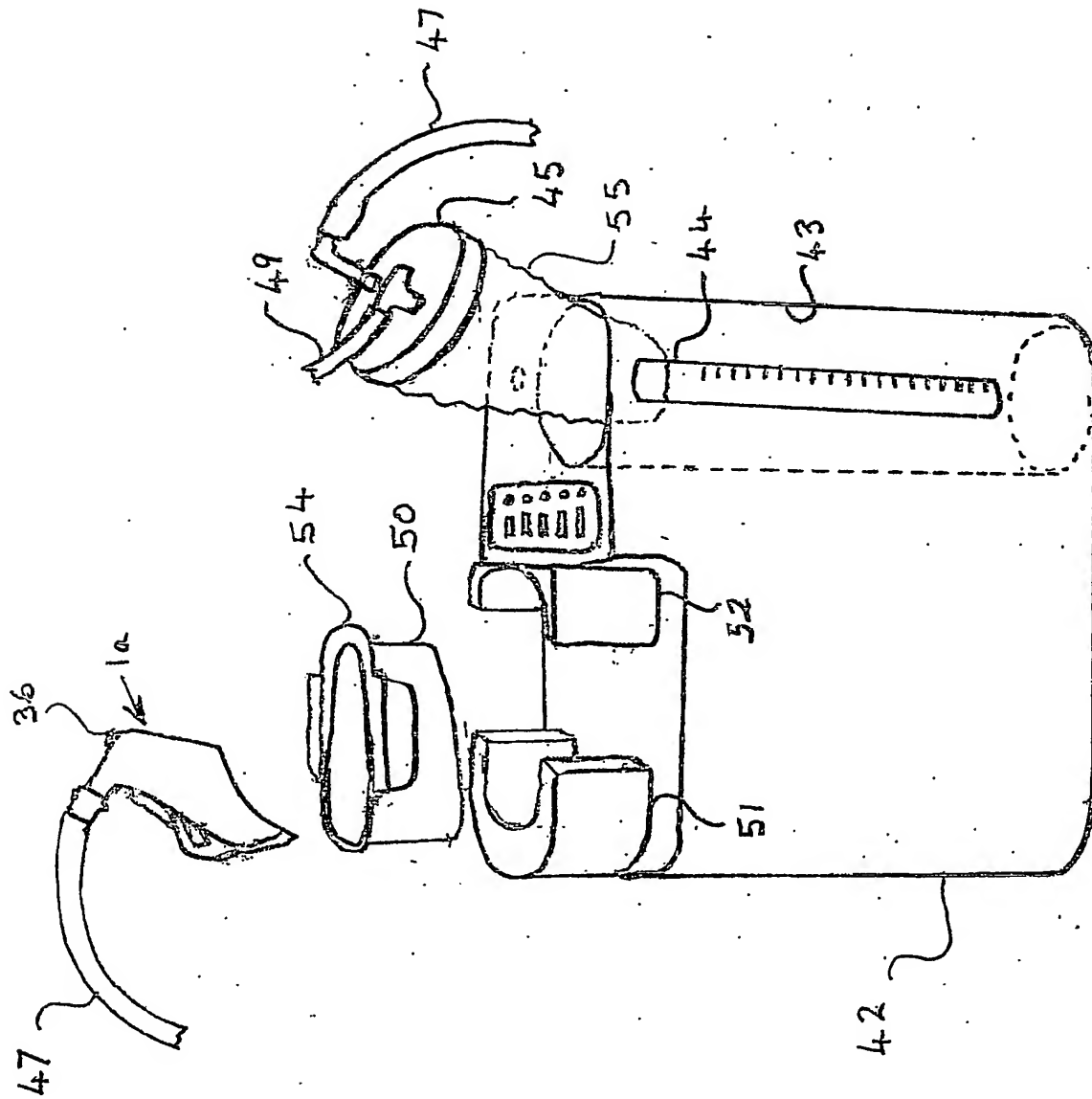


FIGURE 9

THE PATENT OFFICE  
22 SEP 2003  
Received in Patents  
International Unit



**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

**BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**